REMARKS

Status of the Claims

Claims 1-10 and 35 are pending and under consideration in this application. All the pending claims stand rejected. Claims 1, 2, 7, and 8 are amended to specify that the MTBN4 polypeptide is not encoded by the genome of BCG cells. This amendment is supported by the specification, e.g., at page 10, lines 7-18. Moreover, claims 9 and 10 are amended by replacement of the term "*Mycobacteria*" with the term "*Mycobacterium*". This amendment is supported throughout the specification and the claims as originally filed. Moreover, claims 7 and 8 are put in independent form and amended to recite the embodiments of parent claims 1 and 3 and parent claims 2 and 4, respectively. No new matter is added by any of the amendments made herein.

No claims are added or cancelled herein. Therefore, after entry of the present amendments and remarks, claims 1-10 and 35 will be pending and under consideration in the application.

35 U.S.C. § 103(a) rejection

Claims 1-10 and 35 stand rejected as allegedly being unpatentable over WO98/16645 (the '645 application).

From the comments on page 2, line 22, to page 3, line 6, of the Office Action, Applicants understand the Examiner's position to be that, because the '645 application discloses the amino acid sequence of MTBN4 and a nucleic acid sequence that includes a sequence that encodes MTBN4, it renders the present claims obvious. Applicants disagree with this position in light of the following considerations.

Applicants respectfully submit that the '645 application does not disclose or even remotely suggest that the MTBN4 polypeptide not be encoded by the genome of BCG. For example, in this regard, while the inventors of the '645 application were clearly cognizant of the fact that diagnostic assays available at the filing date of the '645 application could not distinguish between infection by *M. tuberculosis* and vaccination with BCG (see, for example, page 2, lines

2-3), nowhere in the '645 application is it suggested that any of the polypeptides it discloses, let alone the one with the amino acid sequence of MTBN4, could be used to distinguish exposure to *M. tuberculosis* from exposure to BCG without exposure to *M. tuberculosis*. For example, none of the experiments described in the '645 application compared subjects known to have been infected with *M. tuberculosis* to those that had been vaccinated with BCG and not been infected with *M. tuberculosis*.

BCG is derived from *Mycobacterium bovis*, the genome of which does encode MTBN4. Thus, in the absence of information to the contrary, one ordinarily skilled in the art would consider it likely that MTBN4 was also encoded by the genome of BCG. In addition, the '645 application contains no teaching that would motivate one ordinarily skilled in the art to test whether it is encoded by the genome of BCG. Moreover, given the state of the art at the priority date of the instant application, even if such an artisan had by some remote chance been motivated to test for the possibility that MTBN4 might not be encoded by the genome of BCG, he or she would not have had a reasonable expectation of success. Clearly, it would not have been mere "common sense" to have tested for the possibility.

In light of the above considerations, Applicants respectfully request that the rejection under 35 U.S.C. § 103(a) be withdrawn.

CONCLUSIONS

Applicant submits that the pending claims patentably define the invention and request that the Examiner permit the pending claims to pass to allowance.

If the Examiner would like to discuss any of the issues raised in the Office Action, Applicant's undersigned representative can be reached at the telephone number listed below.

Enclosed herewith is a request for an automatic extension of time. Please apply the charge for the extension of time and any other charges or credits to Deposit Account No. 06-1050, referencing Attorney Docket No. 07763-043001.

Respectfully submitted,

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